In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 11-301V

Filed: November 6, 2015

H.J.,	*	**TO BE PUBLISHED**
Petitioner,	*	Special Master Hamilton-Fieldman
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Rheumatoid Arthritis ("RA"); Entitlement; Tetanus-Diphtheria-acellular-Pertussis ("Tdap") Vaccine; Immune Complexes.
Respondent.	*	

Ronald Homer, Conway, Homer & Chin-Caplan, Boston, MA, for Petitioner.
Linda Renzi, United States Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On May 13, 2011, H.J. ("Petitioner") filed a petition for compensation pursuant to the National Childhood Vaccine Injury Act of 1986.[2] In her petition, she alleges that a Tetanus-Diphtheria-acellular-Pertussis ("Tdap") vaccine she received on October 10, 2008 caused her to suffer from rheumatoid arthritis ("RA").[3] Petitioner alleges, pursuant to a medical theory based

[1] This Ruling was originally filed on August 31, 2015. Ruling, ECF No. 59. On September 14, 2015, Petitioner requested her name be redacted to initials, and she moved to amend the ruling accordingly. Motion, ECF No. 61. Respondent filed a Response to Petitioner's Motion on October 28, 2015 and the undersigned granted Petitioner's Motion on October 30, 2015. Response, ECF No. 64; Order, ECF No. 65. In the reissued Ruling, Petitioner's name is replaced with her initials; the remainder of the Ruling is unchanged.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. § 300aa-10-§ 300aa-34 (2012) ("Vaccine Act" or the "Act"). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

[3] Rheumatoid Arthritis is "a chronic systemic disease primarily of the joints, usually polyarticular, marked by inflammatory changes in the synovial membranes and articular structures and by muscle atrophy and rarefaction of the bones. In late stages deformity and

on an immune complex mediated response and molecular mimicry, that her immune system was predisposed to autoimmune diseases such as RA, and that the vaccine either caused her to develop RA or significantly aggravated her pre-existing RA.[4] Petitioner's Post-Hearing Brief ("Pet. Brief") at 16-23, filed July 17, 2013. Respondent argues that Petitioner's causation theory lacks scientific and epidemiological support, and that it would be implausible "that it would only take two days for an environmental trigger to cause RA symptoms." Respondent's Post-Hearing Brief ("Resp. Brief"), filed July 17, 2013, at 18-22.

The undersigned finds that Petitioner's theory and the medical records in the case have satisfied the three-pronged test set forth in *Althen v. Secretary of Health and Human Services*. 418 F.2d 1274, 1278 (Fed. Cir. 2005). Specifically, Petitioner has established by preponderant evidence that there is (1) a medical theory causally connecting the injury to the vaccination, (2) with a logical sequence of cause and effect to establish that the vaccination she received was the reason for her injury, and (3) that her injury followed her vaccination within a proximate time period. *Id.* at 1278. Respondent has not rebutted Petitioner's *prima facie* case by showing that her injury was caused by unrelated factors. Therefore, Petitioner has established that she is entitled to compensation.

I. PROCEDURAL HISTORY

Shortly after filing her Petition on May 13, 2011, Petitioner filed affidavits and several medical records. *See generally* Petitioner's Exhibits ("Pet. Exs.") 1-8. On May 11 and 17, 2012, Petitioner filed the expert report of Paul J. Utz, M.D., along with the doctor's curriculum vitae ("CV") and a variety of medical literature the doctor used to support his opinion. *See* Pet. Exs. 9, 9A-J, 10. On October 5, 2012, Respondent filed both an expert report from Lianne S. Gensler, M.D., Dr. Gensler's CV, and a Rule 4(c) Report. *See* Respondent's Exhibits ("Resp. Exs.") A, B.

Petitioner filed additional medical records on November 27, 2012 and January 3, 2013. *See* Pet. Exs. 11-12. On January 4, 2013, Petitioner filed a supplemental expert report, with supportive medical literature, from Dr. Utz. *See* Pet. Exs. 13, 13A. Over the next few months, Petitioner filed three additional sets of medical records and one additional piece of medical literature. *See* Pet. Exs. 14-16.[5]

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ankylosis develop. The cause is unknown, but autoimmune mechanisms and virus infection have been postulated." *Dorland's Illustrated Medical Dictionary* ("*Dorland's*"), 157 (32nd. ed. 2012).

[4] Petitioner did not argue significant aggravation in her petition, and no amended petition was ever filed. The first time this argument is documented in the record is in Petitioner's Pre-Hearing Submission ("Pet. Submission"), filed April 29, 2013, at 1-2. See Subsection (V)(A), herein, for disposition of this issue.

[5] The case was reassigned to the undersigned on March 4, 2013.

On April 29, 2013, Petitioner filed a Pre-Hearing Submission and two additional medical literature articles. *See* Pet. Exs. 17-18. Respondent filed medical articles in support of Dr. Gensler's expert report on April 19, 2013 and May 2, 2013. See Resp. Exs. A1-A3, C, D. On May 9, 2013, Respondent filed her Pre-Hearing Submission, and on May 15, 2013 an entitlement hearing was held in Washington D.C.

During the entitlement hearing, the undersigned referenced an article neither party had presented as evidence, later filed as Court Exhibit 1.[6] *See* Order, filed May 15, 2013, at 1. The undersigned subsequently granted the parties an opportunity to file post-hearing briefs on the new article; the parties, however, did not feel the article submitted by the undersigned required additional briefing. *Id*.; Order, filed June 12, 2013, at 1-2. Respondent did, however, request to file a post-hearing expert report from a new expert, in order to address certain statements concerning immunology made by Dr. Utz during the hearing. *See* Order, filed June 12, 2013, at 1. The undersigned denied Respondent's request, finding that it was clear from Dr. Utz' first expert report that he had claimed expertise in both rheumatology and immunology, and that Respondent had therefore been on notice that Dr. Utz would be discussing both rheumatological and immunological theories at the hearing. *Id.*

After the denial of Respondent's request to file an additional expert report, Respondent's counsel requested a chance to file a post-hearing brief. *Id.* The undersigned granted this request and ordered both parties to file simultaneous post-hearing briefs. *Id.* The parties filed their post-hearing briefs on July 17, 2013. The case is now ripe for a decision on entitlement.

II. MEDICAL HISTORY

A. Pre-Vaccination Medical History

Prior to receiving the Tdap vaccine on October 10, 2008, Petitioner's medical history was significant for several autoimmune diseases: Systemic Sclerosis,[7] noted on July 21, 2000; Sjogren's syndrome,[8] noted on May 9, 2005; Raynaud syndrome,[9] noted on October 24, 2006;

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[6] Jinxia, S., et al., *Prevalence and significance of antibodies to citrullinated human papilloma virus-47 E2345-362 in rheumatoid arthritis*, J. Autoimmun. 2008; 31(2): 131-35.

[7] Systemic Sclerosis is "a systemic disorder of the connective tissue characterized by fibrosis with hardening and thickening of the skin, as well as abnormalities of both microvasculature (telangiectasias) and larger vessels (Raynaud phenomenon); there are also fibrotic degenerative changes in body organs such as the heart, lungs, kidneys, and gastrointestinal tract. It may be confined to the face and hands for long periods or may progress, spread diffusely, and become generalized." *Dorland's*, 1679-80.

[8] Sjogren's syndrome is "a symptom complex of unknown etiology, usually occurring in middle-aged or older women, marked by the triad of keratoconjunctivitis sicca with or without lacrimal

Pulmonary Fibrosis,[10] also diagnosed October 24, 2006; and migraines, noted March 18, 2008. Pet. Ex. 1 at 80. However, she had never been diagnosed with RA, and in 2003, Petitioner tested negative for rheumatoid factor ("RF"), an antibody normally present in people diagnosed with RA. Tr. at 14.

On October 24, 2006, Petitioner saw her treating rheumatologist at Kaiser Permanente ("Kaiser"), Dr. Jeffrey Fong, for a follow-up visit in regards to a swollen finger on her left hand. Pet. Ex. 1 at 289. During that visit, Dr. Fong noted that Petitioner was currently taking one to two tablets of felodipine[11] a day for her Raynaud phenomenon.[12] *Id.* Upon examining Petitioner, Dr. Fong noted that there was some sclerodactyly[13] on Petitioner's proximal interphalangeal joints (that is, the joints between the first and second phalanges of the fingers, also known as the "pip") as well as some facial tightness. *Id.* at 290. Dr. Fong's assessment was scleroderma[14] with mild sclerodactyly, facial involvement and mild upper back involvement, and Raynaud phenomenon with a history of digital ulcerations and foreshortening. *Id.* Dr. Fong directed Petitioner to return for a follow-up in two months. *Id.* at 291.

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gland enlargement, xerostomia with or without salivary gland enlargement, and the presence of connective tissue disease, usually rheumatoid arthritis but sometimes systemic lupus erythematosus, scleroderma, or polymyositis. An abnormal immune response has been implicated." *Dorland's*, 1848.

[9] Raynaud phenomenon is "intermittent bilateral ischemia of the fingers, toes, and sometimes ears and nose, with severe pallor and often paresthesias and pain, usually brought on by cold or emotional stimuli and relieved by heat; it is usually due to an underlying disease or anatomical abnormality. When it is idiopathic or primary it is called *Raynaud disease*." *Dorland's*, 1430. Hereinafter, the term "Raynaud phenomenon" is used interchangeably with "Raynaud disease" and "Raynaud syndrome."

[10] Pulmonary Fibrosis is "chronic inflammation and progressive fibrosis of the pulmonary alveolar walls, with steadily progressive dyspnea, resulting finally in death from oxygen lack or right heart failure." *Dorland's*, 704.

[11] Felodipine is "a calcium channel blocking agent used as a vasodilator in the treatment of hypertension." *Dorland's*, 687.

[12] *See supra* note 11. Petitioner's Raynaud phenomenon started when she was either 14 or 16, after she was in a motor vehicle accident. Pet. Ex. 14 at 69; Pet. Ex. 1 at 310.

[13] Sclerodactyly is "localized scleroderma of the digits, as in acrosclerosis." *Dorland's*, 1679. *See infra* note 14 for a definition of scleroderma.

[14] Scleroderma is "chronic hardening and thickening of the skin, a finding in various diseases." *Dorland's*, 1679.

Petitioner returned to Dr. Fong's office on January 18, 2007 for her follow-up appointment. Pet. Ex. 1 at 297. Dr. Fong observed some mild blanching of Petitioner's extremities, but no ulcers. *Id.* at 298. Petitioner did have some mild sclerodactyly to her "MCP" (metacarpophalangeal) joint[15] with minimal facial involvement. *Id.* Petitioner's joints were evaluated as "ok" during this visit and she was ordered to continue taking felodipine for her Raynaud phenomenon. *Id.*

Petitioner saw Dr. Fong again before her scheduled follow-up, on February 6, 2007, because her Raynaud disease had worsened. *Id.* at 300. Petitioner indicated that her Raynaud disease was worsening at work because her supervisor would not let her use a heater. *Id.* Dr. Fong observed small digital ulcers on Petitioner's right third digit, but with no clear infection. *Id.* Petitioner also had small scars on her second digital area. *Id.* Dr. Fong concluded that Petitioner's disease had worsened, and he suggested she try the new Levitra[16] pill and to continue with her current dose of felodipine. *Id*. at 301.

On April 4, 2007, Petitioner presented to Dr. Fong with complaints that her "finger [was] still turning color," and that the sore on her finger was now "leaking mild clear yellow things." Pet. Ex.1 at 15. Petitioner informed Dr. Fong that she had stopped taking felodipine over a month ago, and that the Levitra he had prescribed had been denied because her insurance would not cover anything over 15 pills. *Id.* Dr. Fong directed Petitioner start Keflex,[17] restart her felodipine, start taking the Levitra (he changed the prescription to 15), and to take two Vicodin at night as needed. *Id.*

Petitioner returned to Dr. Fong for a check up on May 22, 2007. Pet. Ex. 1 at 304. Dr. Fong observed small scars on the digital tips of the second and third fingers on Petitioner's right hand as well as the third finger of her left hand. *Id.* Petitioner continued to have mild sclerodactyly on her MCP joint, though Dr. Fong again noted that Petitioner's joints were "ok." *Id.* Dr. Fong's assessment was that Petitioner's Raynaud phenomenon was stable, although she continued to suffer from scleroderma. *Id.* Dr. Fong ordered Petitioner to continue with her current medications and to take home blood pressure readings three to four times a week. *Id.* A follow-up was scheduled for three to four months later. *Id.* at 305.

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[15] Metacarpophalangeal means "pertaining to the metacarpus and phalanges;" the metacarpus is "the part of the hand between the wrist and the fingers, its skeleton being five cylindric bones (metacarpals) extending from the carpus to the phalanges." *Dorland's*, 1142.

[16] Levitra is "a phosphodiesterase inhibitor that relaxes the smooth muscle of the penis, thereby facilitating blood flow to the corpus cavernosum; used to treat erectile dysfunction in impotence therapy." *Dorland's*, 1031, 1868. Presumably it was prescribed for an off-label purpose. *See, e.g.*, Janis Kelly, *PDE5 inhibitors look widely effective in Raynaud's*, http://www.medscape.com/viewarticle/538492 (last visited Aug. 21, 2015).

[17] Keflex is an antibiotic. *Dorland's*, 330-31; 978.

Petitioner went back to Kaiser on July 13, 2007 for a complaint unrelated to her Raynaud disease or scleroderma. Pet. Ex. 1 at 306. Petitioner saw nurse practitioner Phyllis Moore, who performed a physical examination. *Id.* at 306-07. During the examination, Nurse Moore noted that Petitioner had no joint tenderness, deformity or swelling. *Id.* at 307. As of this visit, Petitioner was taking felodipine, Cephalexin, Hydrocodone-Acetaminophen, and prenatal vitamins. *Id.* at 306.

On August 13, 2007, Petitioner returned to Kaiser and saw Anne Regenstein, M.D., for a pregnancy consultation. *Id.* at 310. During this visit, Petitioner informed Dr. Regenstein that her major health concerns were the periodic ulcers on her hands. *Id.* Petitioner also informed Dr. Regenstein that she was physically active, taking spin and kickboxing classes three times a week. *Id.* Dr. Regenstein noted that Petitioner was not currently on any medications and that, overall, her disease seemed under control. *Id.* at 311. Before discussing with Petitioner the risks involved with getting pregnant, Dr. Regenstein planned to consult with Dr. Fong in order to have a more informed discussion with Petitioner. *Id.* This discussion took place on August 16, 2007. *Id.* at 312. Dr. Regenstein and Dr. Fong and were in agreement that Petitioner was doing fairly well and had a good prognosis for pregnancy. *Id.*

On August 29, 2007, Petitioner saw a nurse practitioner for an "Endocrine Consult" precipitated by some abnormal thyroid results from the lab. Pet. Ex. 1 at 314. The endocrinologist diagnosed Petitioner with hyperthyroidism.[18] *Id.* at 316. During this visit, Petitioner indicated that she had stopped her medications because she wanted to get pregnant, and that her cold intolerance was less problematic during the warmer months. *Id.* at 315.

Petitioner saw Dr. Fong on September 17, 2007. *Id.* at 318. Dr. Fong noted that Petitioner had a mild increase in her Raynaud syndrome, but no pain or ulcers. *Id.* During the examination, Dr. Fong noted that Petitioner's joints were "ok" and that her extremities had some mild blanching but no ulcers. *Id.* at 319. Dr. Fong recommended that Petitioner consider taking Levitra or nifedipine[19] if her Raynaud returned, and to see him for a follow-up in three months. *Id.* at 320.

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[18] Hyperthyroidism is "a condition caused by excessive production of iodinated thyroid hormones; characteristics include goiter tachycardia or atrial fibrillation, widened pulse pressure, palpitations, fatigability, nervousness and tremor, heat intolerance and excessive sweating, warm, smooth, moist skin, weight loss, muscular weakness, excessive defecation, emotional lability, and ocular signs such as stare, slowing of eyelid movements, photophobia, and sometimes exophthalmos." *Dorland's*, 897. Both experts stated that Petitioner's thyroid disease was autoimmune in nature. *See* Pet. Ex. 9 at 6; Tr. at 109.

[19] Nifedipine is "a calcium channel blocking agent used as a coronary vasodilator in the treatment of coronary insufficiency and stable angina pectoris, and as an antihypertensive." *Dorland's*, 1276.

On January 28, 2008, Petitioner returned to Dr. Fong's office. Pet. Ex. 1 at 322. Petitioner complained of a mild increase in her Raynaud phenomenon with some small ulcers which had improved. *Id.* Petitioner also complained that she had experienced periodic mild aches in her fingers and left knee. *Id.* at 323. On observation, Dr. Fong noted that Petitioner had some mild sclerodactyly and some cyanosis[20] on a couple of fingers. *Id.* Dr. Fong again noted that Petitioner's joints were "ok" though he listed joint pains in his assessment of Petitioner's condition. *Id.* at 323-24. Doctor Fong prescribed nifedipine for Petitioner's Raynaud and hydrocodone for any severe pain. *Id.*

Petitioner returned to Kaiser several times following her January 28, 2008 appointment with Dr. Fong; however, none of the visits were with Dr. Fong, and none of them had any relation to her Raynaud disease, scleroderma or Sjogren's syndrome (although she did complain of worse "dry mouth due to Sjogren's syndrome" at a June 30, 2008 appointment regarding a sinus infection). *Id.* at 327-42. Moreover, none of these visits mentions any concerns with Petitioner's joints.

B. Post Vaccination Medical History

On October 10, 2008, Petitioner received the Tdap vaccine Adacel for prophylactic purposes. Pet. Ex. 1 at 345; Pet. Ex. 5 at 1. During this visit, Petitioner was examined by her primary care doctor's nurse practitioner ("NP") Ms. Lunde. Pet. Ex. 1 at 343. Petitioner informed NP Lunde that she had been experiencing left elbow pain for the last six weeks. *Id.* Petitioner explained that the pain was worse in the mornings. *Id.* Upon examination, NP Lunde noted no joint tenderness, deformity, or swelling. *Id.* at 344. However, Petitioner's elbow did have lateral tenderness and muscular tenderness. *Id.* NP Lunde concluded that Petitioner was suffering from an elbow sprain. *Id.* at 346.

On October 16, 2008, six days after receiving the vaccine, Petitioner called Dr. Fong's office and requested an appointment. Pet. Ex. 1 at 91. On October 20, 2008, Petitioner again called Dr. Fong's office requesting an appointment, which was scheduled for October 31, 2008. *Id.* at 92. Petitioner called Kaiser on October 24, 2008, seeking an earlier appointment. No earlier appointments were available, so Petitioner spoke on the phone with Kenneth Lee M.D. *Id.* at 93-95. Petitioner indicated that her chief symptoms were pain and stiffness in all of her joints as well as swollen fingers that began after she received the Tdap vaccine. *Id.* Dr. Lee prescribed three 600mg Ibuprofen tablets a day for pain. *Id.* at 93.

Petitioner had an appointment with Dr. Fong on October 31, 2008 with a chief complaint of joint pain. Pet. Ex. 1 at 352. Petitioner indicated that the joint pain started after her Tdap shot and that she was experiencing swelling and moderate migratory pain. *Id.* at 352-53. Upon examination, Dr. Fong noted that Petitioner had swelling and tenderness on the pip joint of her

[20] Cyanosis is "a bluish discoloration, especially of the skin and mucous membranes due to excessive concentration of deoxyhemoglobin in the blood." *Dorland's*, 452.

right fifth finger, swelling and tenderness on her right second, third, and fourth metatarsophalangeal[21] joints ("MTP joints"), and tenderness in her knees, especially her right, although no warmth or swelling was noted. *Id.* at 354. Dr. Fong noted that Petitioner's wrists, MCP joints, other pip joints, elbows, shoulders, ankles, and left foot were "ok." *Id.* Dr. Fong's assessment was that Petitioner was suffering from inflammatory polyarthritis. *Id.* at 355. However, Dr. Fong was unable to identify a cause for the polyarthritis, noting that it could be post-tetanus serum sickness, scleroderma-related, or possibly an overlap syndrome[22] with Rheumatoid Arthritis ("RA"). *Id.* Dr. Fong prescribed a trial of prednisone, two 5mg tablets every morning for a week, after which Petitioner was to taper the dosage over the next two weeks. *Id.* at 356. Petitioner was to make an appointment to see Dr. Fong again in three months. *Id.*

On November 12, 2008, Petitioner called NP Lunde and indicated that the prednisone Dr. Fong had prescribed was not working. *Id.* at 96-97. Petitioner indicated that her arm was sore for two days after getting the Tdap vaccine and that she had been experiencing pain in her joints since receiving the shot. *Id.* Petitioner called NP Lunde again on November 19, 2008, after being unable to get in contact with Dr. Fong. *Id.* at 100. Petitioner reiterated that the prednisone was not working and that she was still experiencing joint pain. *Id.* Petitioner also indicated that her hands had started swelling since taking the prednisone. *Id.* That same day, Petitioner submitted a VAERS[23] report stating that two days after receiving her Tdap vaccine she started experiencing joint pain in her elbows, knees, hands, shoulders and feet. Pet. Ex. 6 at 2. Petitioner listed October 13, 2008, three days after she received the vaccine, as the date of the onset of her symptoms. *Id.*

On November 20, 2008, Petitioner underwent X-Rays of her hands and feet to evaluate her for possible RA. Pet. Ex. 1 at 102-07. The radiologist found the X-Rays of Petitioner's right foot to be unremarkable. *Id.* at 104. Petitioner's left foot showed "[n]onspecific subchondral

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[21] Metatarsophalangeal means "pertaining to the metatarsus and the phalanges of the toes." *Dorland's*, 1145.

[22] Overlap syndrome is "any of a group of connective tissue disorders that either combine scleroderma with polymyositis or systemic lupus erythematosus or combine systemic lupus erythematosus with rheumatoid arthritis or polymyositis." *Dorland's*, 1842. *See also* Tr. at 89-90.

[23] VAERS ("Vaccine Adverse Events Reporting System") is a database created, pursuant to the Vaccine Act, by the FDA and the Centers for Disease Control and Prevention to receive reports about adverse events which may be associated with vaccines. *See* Vaccine Adverse Event Reporting System, available at https://vaers.hhs.gov/about/index. *See also Nance v. Sec'y of Health & Human Servs.*, No. 06-0730V, 2010 WL 3291896, at *9 (Fed. Cl. Spec. Mstr. July 30, 2010) (discussing that VAERS is a surveillance system that accepts "voluntarily submitted" reports of events from manufacturers, health care workers and patients, and the experiences reported are unsolicited and reflect a concern of a possible relationship to vaccination).

lucency along the navicular bone [and] … along the head of the third proximal phalanx," *id.* at 103, and her hands also showed nonspecific subchondral lucency. *Id.* at 105-06. Dr. Fong reviewed these X-Rays on December 3, 2008, noting that they were "good"—with "[n]o signs of arthritis damage to bones or joints." *Id.* at 285.

Petitioner also had lab work done in late 2008. Pet. Ex. 1 at 361. Dr. Fong called Petitioner on December 3, 2008, to inform her that the lab results showed "[h]igh CCP and RF." Pet. Ex. 1 at 108.[24] Dr. Fong's suspected diagnosis was "[RA] superimposed on scleroderma." *Id.*

Petitioner returned to Dr. Fong's office on December 12, 2008, with a chief complaint of RA. Pet. Ex. 1 at 359. Petitioner noted no improvement in her RA symptoms from either low dose prednisone or hydroxychloroquine.[25] *Id.* Petitioner reported "trouble" with her hands, wrists, knees and feet. *Id.* Petitioner also complained that she was having trouble walking and that she was experiencing morning stiffness lasting half the day, swelling, and severe achy and sharp pain. *Id.* at 359-60. On observation, Dr. Fong noted that Petitioner had polyarthritis in her pip, MCP bilaterally, and her left wrist. *Id.* at 360. Petitioner's knees were warm and tender with mild swelling in the left one. *Id.* Petitioner was also displaying swelling and pain in her MTP. *Id.* at 361. However, Dr. Fong observed that there was no polyarthritis in Petitioner's elbows and shoulders and that Petitioner's ankles were "ok." *Id.* at 360. Dr. Fong's assessment was that Petitioner suffered from RA which was probably in overlap with her scleroderma. *Id.* at 362. To help treat Petitioner's pain, Dr. Fong injected her with DepoMedrol[26] and Xylocaine[27] in both of her knees and her left wrist. *Id.* Dr. Fong also prescribed methotrexate[28] for

[24] "CCP" is cyclic citrullinated peptide. Tr. at 14. Measurement of anti-CCP antibody levels has recently been discovered as a more specific tool than rheumatoid factor ("RF") to diagnose the existence of RA. Tr. at 14-15, 126-27.

[25] Hydroxychloroquine sulfate is "a … compound with antiprotozoal and anti-inflammatory properties, used for suppression and treatment of malaria, for suppression of lupus erythematosus, and as an anti-inflammatory disease-modifying antirheumatic drug in treatment of rheumatoid arthritis." *Dorland's*, 881.

[26] Depomedrol is a medication "administered topically as anti-inflammatory, by intramuscular injection in replacement therapy for adrenocortical insufficiency, and by intra-articular, intramuscular, intralesional, or soft-tissue injection as an anti-inflammatory and immunosuppressant in a wide variety of disorders." *Dorland's*, 492, 1154.

[27] Xylocaine is "a trademark for preparations of lidocaine." *Dorland's*, 2088.

[28] Methotrexate is "a folic acid antagonist that acts by inhibiting synthesis of DNA, RNA, thymidylate, and protein …. Used as an antipsoriatic and antiarthritic in the treatment of severe, recalcitrant, disabling psoriasis and severe rheumatoid and psoriatic arthritis." *Dorland's*, 1151.

Petitioner, with instructions to increase the dosage each month if her symptoms did not improve. *Id.* at 363.

Following her December 12, 2008 appointment, Petitioner participated in multiple physical therapy sessions to help with her RA, and also continued to see Dr. Fong for regular follow-up visits. *Id.* at 367-442; *see generally* Pet. Ex. 11. For the most part, Petitioner's RA improved, although she still experienced pain and swelling in multiple joints.[29] Petitioner was seen by Elena Torello, M.D. on May 7, 2010 for a routine physical exam required by her college program. *Id.* at 438-39. During the examination, Dr. Torello noted that Petitioner's fingers were puffy but that her arthritis was asymptomatic. *Id.* This was attributed to Petitioner's usage of Humira.[30] *Id.* Petitioner continued to improve and on December 20, 2010, Petitioner reported that she was able to participate in vigorous activities and was exercising on the stationary bike for 30 minutes every other day. Pet. Ex. 11 at 118. Humira continued to be effective in controlling Petitioner's RA symptoms, although she experienced a flare in symptoms around April 10, 2012. *Id.* at 192-93.

III. QUALIFICATIONS OF THE EXPERTS

A. Petitioner's Expert: Paul Utz, M.D.

Paul J. Utz, M.D., testified on behalf of Petitioner. *See* Tr. at 2. Dr. Utz is currently a full professor at Stanford University School of Medicine. Tr. at 6. At Stanford, Dr. Utz runs the M.D./Ph.D. program, is the adult rheumatology fellowship director, teaches an immunology class (among others) to medical students, and regularly sees patients in clinic and on rounds. Tr. at 6-7. Dr. Utz received a medical degree from Stanford University, was a Clinical Fellow in Immunology and Rheumatology at Brigham and Women's Hospital, and was an instructor at Harvard Medical School. *See* Tr. at 5-6; Pet. Ex. 10.

B. Respondent's Expert: Lianne S. Gensler, M.D.

Lianne S. Gensler, M.D., testified on behalf of Respondent. *See* Tr. at 2. Dr. Gensler is currently an assistant clinical professor of medicine at the University of California, San Francisco, where she is the director of the ankylosing spondylitis clinic, performing epidemiologic research and clinical trial research. Tr. at 107. In addition, Dr. Gensler has a

[29] During a visit with Dr. Fong on September 3, 2009, Petitioner stated that her arthritis pain had been worse for the last three weeks since she stopped using prednisone. Pet. Ex. 1 at 414. This was the first visit with Dr. Fong since being diagnosed with RA at which Petitioner did not indicate she was feeling better.

[30] Humira is "a recombinant human IgG1 monoclonal antibody that binds to and blocks the action of tumor-necrosis factor α, used to alleviate the signs and symptoms of and inhibit the progression of structural damage in rheumatoid arthritis." *Dorland's*, 25, 873.

clinical practice where she sees many RA patients. Tr. at 107-08. She received her medical degree from the University of California, Irvine, and did her residency, fellowship, and chief residency at University of California, San Francisco. Tr. at 106.

IV. APPLICABLE LEGAL STANDARD

To receive compensation under the Program, Petitioner must prove either 1) that she suffered a "Table Injury" — i.e., an injury falling within the Vaccine Injury Table[31] — corresponding to one of her vaccinations, or 2) that Petitioner suffered an injury that was actually caused by a vaccine. *See* 42 U.S.C.A. § 300aa-13(a)(1)(A); *see also* § 300aa-11(c)(1). Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321-22 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)). Petitioner has not claimed a Table Injury, and an examination of the record has not revealed any possible Table Injury.

Absent a Table Injury, Petitioner must satisfy all prongs of the test established by the Federal Circuit in *Althen v. Secretary of the Department of Health and Human Services*. 418 F.3d 1274, 1279 (Fed. Cir. 2005). The *Althen* test requires the petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury ("*Althen* Prong One"); (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury ("*Althen* Prong Two"); and (3) a showing of a proximate temporal relationship between vaccination and injury ("*Althen* Prong Three")." *Id.* To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *Id.*

The preponderance of the evidence standard has been interpreted to mean that the Petitioner must show that the fact is more likely than not. *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n. 2 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). "[T]he purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280.

In determining whether Petitioner is entitled to compensation, the undersigned will consider all relevant, material contained in the record. 42 U.S.C.A. § 300aa-13(b)(1). That material can include circumstantial evidence. *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). As the finder of fact, the undersigned is "entitled—indeed, expected—to make determinations as to the reliability of the evidence presented…and, if

[31] The Vaccine Injury Table "lists the vaccines covered under the Act; describes each vaccine's compensable, adverse side effects; and indicates how soon after vaccination those side effects should first manifest themselves. Claimants who show that a listed injury first manifested itself at the appropriate time are prima facie entitled to compensation." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011) (citing 42 U.S.C.A. § 300aa-14(a)).

appropriate, as to the credibility of the persons presenting that evidence." *Moberly*, 592 F.3d at 1326. The Vaccine Act was created to award compensation to vaccine-injured persons "quickly, easily, and with certainty and generosity." *Graves v. Sec'y of Health & Human Servs.*, 109 Fed Cl. 579, 595 (2013) (quoting H.R. Rep. No. 99-908 at 3). Therefore, "close calls regarding causation are resolved in favor of injured" petitioners. *Althen*, 418 F.3d at 1280; *see also Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999).

If Petitioner satisfies all three prongs of *Althen* by a preponderance of the evidence, she establishes a *prima facie* case. *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1149-51 (Fed. Cir. 2007). After Petitioner has established a *prima facie* case, the burden shifts to Respondent to demonstrate, also by a preponderance of the evidence, that the injury was actually caused by factors unrelated to the administration of the vaccine. *Walther*, 485 F.3d at 1151; 42 U.S.C.A. § 300aa–13(a)(1)(B). Accordingly, "[i]f the evidence is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 550 (Fed. Cir. 1994).

V. ANALYSIS

A. Causation-in-Fact Versus Significant Aggravation

Both experts opined that, from a medical perspective, Petitioner was "more likely than not in the preclinical stage[32] of RA at the time of her vaccination." Pet. Ex. 9 at 8-9, Tr. at 138. *See also* Pet. Ex. 9, Tab E.[33] The undersigned therefore struggled with whether this case should be analyzed as one asserting causation-in-fact or significant aggravation. Petitioner had not had any laboratory test results confirming that preclinical state, however, *see* Pet. Ex. 1 at 55, nor did she have symptoms of RA prior to vaccination.[34] Application of the Act is triggered by "the first symptom or manifestation of onset" of an alleged vaccine-related injury. 42 U.S.C.A. § 300aa-16(a)(2). Because the undersigned now finds that the first symptom or manifestation of Petitioner's RA did not occur until after vaccination, the undersigned views Petitioner's theory as one of causation-in-fact rather than significant aggravation, and will analyze it accordingly.

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[32] Preclinical means "before a disease becomes clinically recognizable." *Dorland's* at 1508. It is also defined as "[b]efore the onset of disease." *Stedman's Medical Dictionary* at 1553 (28th. ed. 2006).

[33] Deane, K., et. al., *The number of elevated cytokines and chemokines in preclinical seropositive rheumatoid arthritis predicts time to diagnosis in an age-dependent manner*, Arthritis Rheum. 2010; 62(11): 3161-72, at 3161-62 ("Multiple studies have demonstrated that levels of disease-related biomarkers may be elevated prior to the onset of symptomatic rheumatoid arthritis;" this "preclinical" period of RA "may be present for many years prior to the onset of articular symptoms.")

[34] The lack of pre-vaccination RA symptoms was disputed by Respondent. Discussion of that issue can be found in the *Althen* Prong Two analysis below.

B. *Althen* Prong One: Medical Theory

To satisfy the first prong of the *Althen* test, Petitioner must provide "a medical theory causally connecting the vaccination and the injury." *Althen*, 418 F.3d at 1278 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F. 2d 1144, 1148 (Fed. Cir.1992)). Petitioner's theory must show that it is more likely than not that the vaccine she received "can" cause the type of injury Petitioner alleges the vaccine caused. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006).

The medical theory set forth by the Petitioner must be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548-49. However, the theory cannot be baseless or completely speculative; it must be informed by "sound and reliable medical or scientific explanation." *Id.* at 548*; see also Veryzer v. Sec'y of Health & Human Servs.*, 98 Fed. Cl. 214, 223 (2011) (noting that under 42 U.S.C.A. § 300aa-13(b)(1) and Vaccine Rule 8(b)(1), special masters must consider only evidence that is both "relevant" and "reliable"). When a petitioner proffers a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in determining how much weight to afford the offered opinion. *See Broekelschen v. Sec'y of Health & Human Servs.*, 618 F. 3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); *Perreira v. Sec'y of Health & Human Servs.*, 33 F.3d 1375, 1377 n. 6 (Fed. Cir. 1994) ("An expert opinion is no better than the soundness of the reasons supporting it") (citing *Fehrs v. United States*, 620 F.2d 255, 265 (Ct. Cl. 1980)).

As noted above, both parties' experts agreed that Petitioner was in the preclinical stage of RA before her vaccination.[35] Pet. Ex. 9 at 8-9; Tr. at 138. Both experts also agreed that Petitioner suffered from more than one connective tissue disorder and that she satisfied the criteria for overlap syndrome. Pet. Ex. 9 at 8; Resp. Ex. A at 6. Petitioner's theory of causation therefore focused on the potential impact of a Tdap vaccine on an individual with overlap syndrome and preclinical RA. Dr. Utz opined that an individual with preclinical RA "is at increased risk to develop overt disease if they encounter an environmental trigger such as an infection, vaccination, ultraviolet radiation, or certain chemicals." Pet. Ex. 9 at 8. He also argued that "subjects with preexisting inflammatory conditions such as Systemic Sclerosis, Sjögren's syndrome, or autoimmune thyroid disease are at increased risk to develop another inflammatory condition such as RA following immunizations with Tdap, influenza, hepatitis B, or other vaccines." Pet. Ex. 9 at 10. Finally, Dr. Utz noted that "[m]any arthritides including. . .RA. . .are postulated to be. . .or known to be. . .caused by exposure to an infectious antigen or foreign antigen" such as that presented by a vaccine. Pet. Ex. 9 at 13.

[35] Dr. Gensler argued, alternatively, that Petitioner's RA was actually symptomatic before she received the vaccine. That argument is addressed in the *Althen* Prong Two analysis.

In support of these arguments, Dr. Utz cited two articles identifying tetanus vaccination and a pulmonary infection as environmental triggers, exposure to which caused RA in the subjects of the articles. *See* Pet. Ex. 9, Tab H;[36] Pet. Ex. 9, Tab I.[37] In support of his opinion that vaccination could trigger RA in patients with preexisting inflammatory conditions, Dr. Utz also argued that the percentage of patients excluded from the study cohort in the Ray and Black study because of preexisting inflammatory conditions was far greater "than one would expect by chance alone." Pet. Ex. 9 at 10; *see also* Pet. Ex. 9, Tab G.[38]

Dr. Utz asserted that abrupt onset of severe disease would be consistent with his theory that the introduction of an antigen to an individual with a predisposed, hyperactive immune system can trigger an immune complex-mediated inflammatory response from existing B and T lymphocytes. Pet. Ex. 9 at 8-9, 13; Tr. at 25. Dr. Utz stated that six to twenty-one days would be "a very typical window for development of such an immune response." Pet. Ex. 9 at 13. Thereafter, the disease process would become autoimmune as the patient's T cells began identifying and attacking the linear peptides in the patient's own cells in place of the original antigen. Tr. at 172; *see also* Pet. Ex. 9 at 11-13.

Dr. Gensler declined to opine on the immunological aspects of the Prong One theory offered by Petitioner. Dr. Gensler is not an immunologist and did not believe her expertise was sufficient to allow her to testify in this area. Tr. at 143-44. However, from her expertise as a rheumatologist, and using epidemiological evidence, Dr. Gensler did question the part of Petitioner's theory that concerns the triggering potential of vaccines. Tr. at 144-50. Dr. Gensler testified that no environmental trigger is needed to prompt the onset of RA in a patient with overlap syndrome or preclinical RA. Tr. at 127-29. Dr. Gensler testified that she rarely sees an environmental trigger associated with the onset of RA in her patients. Tr. at 128.

Dr. Gensler also cited the Institute of Medicine (IOM) publication, *Adverse Effects of Vaccines—Evidence and Causality* [hereinafter "IOM publication"], which concluded that there was not enough evidence to accept or reject a causal relationship between Tdap and the development of RA. Resp. Ex. A at 6; Resp. Ex. A1.[39] Dr. Gensler noted that, according to the

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[36] Sharma, A., et al., *Vaccination as a triggering agent for the development of rheumatoid arthritis*, Int. J. Rheum. Dis. 2011; 14(1): 8-9.

[37] Iwata, H., et al., *Emergence of erosive polyarthritis coincident with Mycobacterium kansassi pulmonary infection in a patient with systemic sclerosis-rheumatoid arthritis overlap syndrome*, Clin. Exp. Rheumatol. 1999; 17(6): 757-58.

[38] Ray, P., Black, S., et al., *Risk of rheumatoid arthritis following vaccination with tetanus, influenza and hepatitis B vaccines among persons 15-59 years of age*, Vaccine 2011; 29(38): 6592-97.

[39] Committee to Review Adverse Effects of Vaccines, Institute of Medicine of the National Academies, *Adverse Effects of Vaccines – Evidence and Causality*, 567-571.

IOM publication, there was no increase of reported cases of RA within five years after receiving a vaccine. Resp. Ex. A at 6.

The undersigned often relies on epidemiological evidence such as that underlying the IOM publication. However, particularly in the Prong One context, its persuasiveness is tempered by the fact that, while it may show that a vaccine has not caused a particular injury, at least to a statistically relevant extent, it cannot show that the vaccine cannot cause that particular injury. In the present case the epidemiological evidence was also of limited value because, as Dr. Utz pointed out, well-done studies like this are generally limited to patients with healthy immune systems; patients with abnormal immune systems are excluded, and Petitioner's theory is premised on the vaccinee having a compromised immune system. Pet. Ex. 9 at 10; Tr. at 74-76.

The undersigned agrees with Respondent that an environmental trigger is not required for preclinical RA to develop into clinical RA. However, the undersigned finds persuasive Petitioner's theory that an environmental trigger such as a vaccine can cause preclinical RA to develop into clinical RA. The triggering role of the vaccine postulated by Petitioner explains to the undersigned's satisfaction an acute and severe onset of an otherwise chronic condition, and the transition from an inflammatory condition to an autoimmune one. The undersigned finds Petitioner's theory sufficiently persuasive to meet Petitioner's burden of proof under *Althen* Prong One.

C. *Althen* Prong Two: Logical Sequence of Cause and Effect

To satisfy the second prong of the *Althen* test, Petitioner must establish "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. That is, Petitioner must show, by preponderant evidence, that the vaccination Petitioner received *did* cause the injuries she alleges they caused. *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions; she is not required to offer "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Id.* at 1325.

Prior to vaccination, Petitioner suffered from several autoimmune diseases – systemic sclerosis (scleroderma), Sjögrens syndrome, and autoimmune thyroid disease. Pet. Ex. 9 at 13; Tr. at 109. The experts agreed she met the criteria for overlap syndrome. *Id.* Petitioner was tested for RF in 2003, with negative results. Pet. Ex. 1 at 55. Results for both RF and anti-CCP were significantly elevated by November 20, 2008, six weeks after her vaccination. Pet. Ex. 1 at 361. The preexisting overlap syndrome, coupled with the positive serology within weeks of symptom onset, led both experts to conclude that Petitioner had preclinical RA at the time of vaccination. Pet. Ex. 9 at 8; Tr. at 81-82, 116, 126-31.

Dr. Utz emphasized that although Petitioner "had an immune system that was already abnormal," Tr. at 82, "her blood tests, history, and examination provided no evidence whatsoever that she had RA." Pet. Ex. 9 at 8; *see also* Tr. at 25-26 ("Nowhere in the medical record could I find evidence that she had synovitis, which is inflammation in the joints, or even significant morning stiffness [prior to receiving the vaccine]."). He also emphasized that the onset of Petitioner's symptomatic RA was "abrupt," Pet. Ex. 9 at 8-9, 13 ("explosive"); Tr. at 12, 14 ("acute"), 22, 25, 82 ("severe"), as opposed to having developed "insidiously," as is the normal course of RA development. Tr. at 21-22, 39, 122. This "explosive" onset, Dr. Utz argued, supports his conclusion that Petitioner's RA was triggered by an environmental factor, namely, the vaccine, which activated existing T cells and antigen-antibody immune complexes to cause the inflammatory symptoms. Tr. at 25-26, Pet. Ex. 9 at 13.

Dr. Gensler did not agree that the vaccine caused Petitioner's RA, because she concluded that Petitioner's symptomatic RA was a manifestation of the overlap syndrome that predated the vaccine. Tr. at 136-37. Although Dr. Gensler conceded that Petitioner did not carry a diagnosis of RA prior to October 10, 2008, Tr. at 137, Dr. Gensler cited several places in Petitioner's medical records on the basis of which she concluded that Petitioner's RA symptoms predated the vaccine.

Dr. Gensler first cited the elbow pain that was part of the reason Petitioner was at the doctor's office the day she received her vaccine. Pet. Ex. 1 at 83. Petitioner saw NP Lunde for this visit, with "[complaints of left] elbow pain [for] 6 weeks, pain worse in am." *Id*. NP Lunde's musculoskeletal exam notes state "no joint tenderness, deformity, or swelling. [Left] elbow lateral tenderness muscuilar tenderness noted." *Id*. at 84. NP Lunde diagnosed an elbow sprain and directed Petitioner to "use elbow support." *Id*. at 85. Dr. Gensler testified that it is very difficult to diagnose RA symptoms in an elbow joint—in her experience, residents misdiagnose it almost 80% of the time, and "nurse practitioners are almost invariably wrong." Tr. at 118. Therefore, Dr. Gensler concluded, NP Lunde misdiagnosed Petitioner's elbow pain as a sprain when in fact it was a symptom of her developing RA. Tr. at 116-19.

The post-vaccination X-Rays of Petitioner's hands and feet were also cited by Dr. Gensler as evidence that clinical RA onset predated Tdap vaccination. Tr. at 123-25; Pet. Ex. 1 at 102-07. The X-Rays were performed to "[e]valuate for rheumatoid arthritis." Pet. Ex. 1 at 103-06. The radiologist at Petitioner's treating facility found the X-Rays of Petitioner's right foot to be unremarkable. Pet. Ex. 1 at 104. Petitioner's left foot showed "[n]onspecific subchondral lucency along the navicular bone [and] … along the head of the third proximal phalanx," *id.* at 103, and her hands also showed nonspecific subchondral lucency. *Id.* at 105-06. Dr. Fong reviewed these X-Rays on December 3, 2008, and noted that they were "good," with "[n]o signs of arthritis damage to bones or joints." *Id.* at 285. Dr. Gensler did not personally review the X-Rays. Tr. at 124, 143. However, in Dr. Gensler's experience, radiologists misdiagnose erosions about 50 percent of the time, so it is not significant that the radiologist who examined the X-Rays did not diagnose these lucencies as possible erosions. Tr. at 126. She also doubted that Dr. Fong personally reviewed the X-Rays. Tr. at 143. Dr. Gensler opined that the

non-specific subchondral lucencies are suggestive of erosions, particularly in a patient with "this disease and demographics." Tr. at 124. Since erosions take time to develop, she opined, it is likely that Petitioner had RA before the Tdap vaccination. Tr. at 125-26.

The undersigned has no doubt that Dr. Gensler is a highly qualified rheumatologist who has treated thousands of patients. She has physically examined those patients and reviewed their X-Rays. As qualified as she is, however, she did not examine Petitioner, and she did not review Petitioner's X-Rays. Contemporaneous medical records are trustworthy documentation of a patient's diagnosis and treatment. *Cucuras v. Sec'y of Health & Human Serv*s., 993 F.2d 1525, 1528 (Fed. Cir. 1993). The undersigned will not override the contemporaneous conclusions of Petitioner's own treating professionals based only on Dr. Gensler's opinion that those treaters' evaluations were wrong. The undersigned finds that the pre-diagnosis elbow pain and the post-diagnosis X-Rays did not show that Petitioner had clinical symptoms of RA before October 10, 2008.

The undersigned found the Prong One theory offered by Dr. Utz to be persuasive; by preponderant evidence Petitioner has shown that the vaccine can cause RA in a patient with overlap syndrome and preclinical disease. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). The facts of Petitioner's case as set forth herein support the application of that theory to her case. The undersigned concludes that Petitioner has shown by preponderant evidence that the vaccine did cause her clinical RA, and she has therefore met her burden of proof under Prong Two of *Althen*.

D. *Althen* Prong Three: Temporal Association

To satisfy the third prong of *Althen*, petitioners must produce preponderant evidence of "a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. This prong helps to establish the connection between the causal theory of Prong One and the more fact-based cause and effect arguments of Prong Two by demonstrating "that the onset of symptoms occurred within a timeframe from which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Petitioner may meet her timing burden by showing: (1) when the condition for which she seeks compensation first appeared after vaccination, and (2) whether the period of symptom onset is "medically acceptable to infer causation." *Shapiro v. Sec'y of Health & Human Servs.*, No. 99-552V, 2011 WL 1897650, at *13 (Fed. Cl. Spec. Mstr. Apr. 27, 2011), aff'd in relevant part and vacated on other grounds, 101 Fed. Cl. 532, 536 (2011).

The onset of RA is usually "insidious." Tr. at 21-22, 39, 122. However, under the theory of causation advanced by the Petitioner, where the manifestation of RA is caused by an environmental trigger administered to an individual with preclinical RA and overlap syndrome, onset occurs abruptly and within a fairly short time after the trigger is introduced. Dr. Utz stated that six to twenty-one days would be an appropriate time frame for such an immune response. Pet. Ex. 9 at 13.

Dr. Gensler testified that her reading of the VAERS report and other records indicated that Petitioner had identifiable RA symptoms no more than two days after administration of the Tdap vaccine. Tr. at 130; *see also* Pet. Ex. 6 at 1, Pet. Ex. 9 at 5. Dr. Gensler relied on three different reports made by Petitioner to support this conclusion. Tr. at 130. First, in her October 24, 2008 request for an appointment, Petitioner indicated that she he had been experiencing joint swelling "ever since" the day of the vaccination. Pet. Ex. 1 at 94; Tr. at 130. Second, Petitioner reported three weeks of joint pain when she was examined by her rheumatologist on October 31, 2008, which would mean her joint pain began on October 10, 2008—the date of vaccination. Pet. Ex. 9 at 5; Tr. at 130. Finally, in her Nov. 19, 2008 VAERS report, Petitioner reported that her joint pain began two days after vaccination. Pet. Ex. 6 at 1; Tr. at 130.

Dr. Utz relied more on the contemporaneous records following the vaccination, rather than information recollected by Petitioner on a later date. Tr. at 99-100. He gave less weight to the statements of Petitioner on October 31, 2008 (complaining of "[three] weeks of joint pain post tetanus shot," Pet. Ex. 1 at 352), and Petitioner's VAERS Report of November 19, 2008 (reporting that joint pain began two days after vaccination). Pet. Ex. 13 at 5-6; Pet Ex. 6 at 1; Tr. at 99-100. Dr. Utz opined that Petitioner's RA symptoms began as early as 6 days after receiving the vaccine October 10, 2008. Tr. at 99. He based this opinion on the calls Petitioner made to her rheumatologist.[40] Tr. at 97. Based on the time frame of these calls, Dr. Utz used a holistic approach to determine onset of RA, placing onset between the first call, when she merely requested an appointment, and the third call when she complained of swelling in her fingers and stiffness in her joints. Pet. Ex. 13 at 6. Dr. Utz reasoned that if her symptoms had started earlier, then she would have called earlier. Pet. Ex. 13 at 6. Dr. Utz testified that the X-Rays taken of Petitioner on November 20, 2008 did not indicate bone mineralization or evidence of erosions, further supporting his theory that RA onset was six to fourteen days after vaccination. Tr. at 161, 23.

The undersigned gives more weight to the approach taken by Dr. Utz because it is based on contemporaneous evidence rather than recollections of the Petitioner. Absent contemporaneous examination by a competent medical professional, it is impossible to determine the precise date of Petitioner's first RA symptom. Therefore, the undersigned concludes that the first symptom of Petitioner's RA occurred between six and fourteen days after vaccination. As this timing is consistent with Petitioner's Prong One theory, the undersigned concludes that the evidence presented satisfies Petitioner's burden to show an appropriate temporal association between the vaccination and the injury under Prong Three of *Althen*.

[40] Petitioner called her rheumatologist to seek an appointment on Oct. 16, 2008; she called again to seek an appointment on October 20, 2008; and on Oct 24, 2008, she called her rheumatologist with complaints of "pain and stiffness in all her joints," as well as "swollen fingers." Pet. Ex. 9 at 6; Pet. Ex. 1 at 91-95.

VI. CONCLUSION

For the reasons set forth above, the undersigned finds that Petitioner has shown by medical records and competent medical opinion that her alleged medical condition was "more likely than not" vaccine-caused, and that she is entitled to compensation. This case is now ready to proceed in damages.

IT IS SO ORDERED.

s/Lisa D. Hamilton-Fieldman
Lisa D. Hamilton-Fieldman
Special Master